REMARKS

Status of the Claims.

Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claims 1 and 16 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (*e.g.*, at page 14, lines 1-6, at page 74, lines 2-8, at page 55, lines 12-21, in the claims as filed, and so forth).

35 U.S.C. §112, Second Paragraph.

Claims 1-4, 6-9, 16-19, and 21-26 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the recited hybridization conditions were allegedly unclear. According to the Examiner it was unclear whe6ther the recitation of "comprising 65°C in 0.2 x SSC" is used in reference to hybridization or to wash conditions. Per the Examiner's recommendation, claims 1 and 16 are amended herein to recite "stringent hybridization conditions comprising washes at 65°C in 0.2 x SSC" thereby obviating this rejection.

35 U.S.C. §112, First Paragraph, description requirement.

Claims 1, 4, 6-13, 21-26, 71, 79, and 82-85 were rejected under 35 U.S.C. §112, first paragraph, as allegedly overbroad because the functional limitation ". . . encoding a transcription factor" encompasses a broad range of structurally and functionally different compounds.

Per the Examiner's recommendation, claims 1 and 16 are amended herein to recite ". . . .transcription factor that binds to, and transactivates the Her-2/neu Ets response element" thereby obviating this rejection.

The Examiner alleged, that the specification "does not appear to provide teachings that the murine sequence of claim 16 binds to and transactivates the Her-2/neu Ets response element. Applicants note however, that the specification generally teaches that ESX is a strong transactivator:

> **The ESX polypeptide appears to be an extremely strong gene transactivator**, as revealed by GAL4 fusion studies showing that the ESX amino acid sequences encoded by *ESX* exon 4 are as powerful as the transactivating sequences of VP16, one of the strongest transactivators known and most often used as a positive control in GAL4 fusion studies. These studies indicate that ESX is most likely "turning on" rather than "turning off" all the genes under its control (*e.g.*, growth factor receptors such as *erb*B2,

> and extracellular matrix proteases such as MMPs, and UPA**). Up-regulation of ESX will therefore turn on (*e.g.*, transactivate) genes under ESX control, while down-regulation of ESX will turn off genes under ESX control**. [emphasis added] (page 55, lines 12-21)

Moreover, Example 5 clearly establishes that human ESX transactivates Her-2/neu. The Examiner has offered no objective basis whereby one of skill would belief the murine ESX would function differently that the human ESX.

Accordingly, Applicants believe both claim 1 and claim 16, as amended herein, are fully enabled and the rejections under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §112, First Paragraph, "new matter".

The Examiner alleged that the recitation "comprising 65°C in 0.2 x SSC" is only used in reference to the wash conditions of a Northern hybridization procedure. The Examiner further alleged that the specification does not teach that stringent conditions may be specifically defined by the recitation "comprising 65 °C in 0.2 x SSC" and alleged that the amendment to claims 1 and 16 constitutes new matter and one of skill in the art would not conclude Applicants were in possession of the claimed invention at the time of filing.. Applicants traverse.

The specification expressly teaches:

> Typically, stringent conditions will be those in which **the salt concentration is less than about 1.0 M sodium ion**, typically about 0.01 to 1.0 M sodium ion concentration (or other salts) at pH 7.0 to 8.3 and the temperature is at least about 30°C for short probes (*e.g.*, 10 to 50 nucleotides) and **at least about 60°C for long probes (*e.g.*, greater than 50 nucleotides)**. [emphasis added} (page 14, lines 1-6)

One of ordinary skill in the art reading the disclosure would readily recognize that a wash comprising 65°C (at least about 60°C) in 0.2 x SSC (less than about 1.0 M sodium ion) would" comprise "stringent conditions" as described in the specification. Accordingly the claim amendments do not comprise new matter and the rejections under 35 U.S.C. §112, first paragraph, on these grounds should be withdrawn.

35 U.S.C. §102.

Claims 1, 2, 6-13, 21-26, 79, and 82-87 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Khola *et al.* (U.S. Patent 5,789,200). Upon an indication of otherwise allowable subject matter, Applicants will file a statement under 37 C.F.R. §1.6089(a).

Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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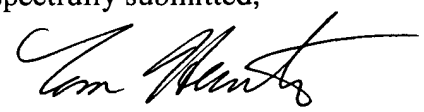
Respectfully submitted,



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